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Meso-zeaxanthin Ocular Supplementation Trial in Normals (MOST N)

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PURPOSE

The centre of the macula has a distinct yellow colour attributable to the presence of a yellow pigment known as macular pigment (MP). MP is made up of the three lipid-like carotenoids meso-zeaxanthin (MZ), lutein (L) and zeaxanthin (Z) (ratio at the macula: 1: 1: 1).[1; 2]

The MOST N (ISRCTN60816411) study was designed to investigate, in a double-blind, randomized placebo controlled fashion, changes in MP optical density (MPOD), and serum concentrations of the macular carotenoids in response to a supplement containing MZ, L and Z , in normal subjects.

METHODS

44 healthy subjects were recruited for this study. 22 subjects were randomized to consume a formulation containing 10.9 mg of MZ, 5.9 mg of L and 1.2 mg of Z (Intervention group [I]), and 22 subjects consumed a placebo containing corn starch and rice flour (Placebo group [P]) everyday with a meal over a six month study period.

At each study visit (Baseline [V1], 3 months [V2], 6 months [V3]) MPOD (at 0.25°, 0.5°, 1° and 1.75° degrees eccentricity) was measured using customized heterochromatic flicker photometry (cHFP) [Fig. 1].

Blood samples were also collected to analyze serum concentrations of L and TZ (total zeaxanthin which includes MZ and Z) by high performance liquid chromatography (HPLC) [Fig. 2]. Additional blood samples were collected at V1 and V3 and sent to Claymon Biomnis Laboratories, Ireland, for full clinical pathology analysis to assess the safety of MZ, L and Z consumption in humans [Table 1].

For MPOD and serum carotenoid data, we conducted repeated measures analysis using a general linear model approach. For the clinical pathology analysis, we used paired-samples t-tests to test for statistical differences between V1 and V3.

Figure 1. cHFP

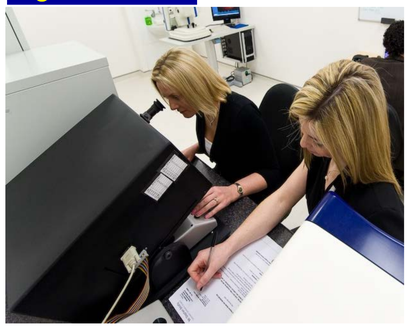
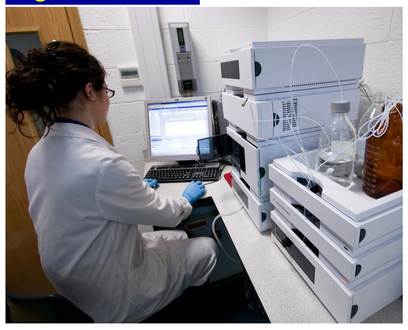


Figure 2. HPLC



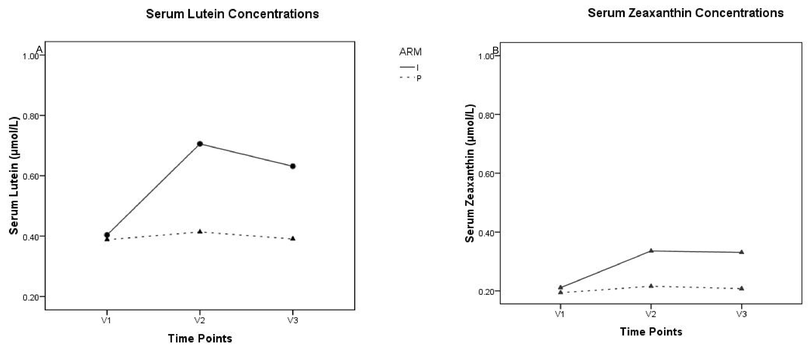
RESULTS

Serum Carotenoid Analysis

There was a statistically significant increase in serum concentrations of L and TZ* (µmol/L) from baseline at V2 and V3 in the I group ($p < 0.005$, for all). As expected, there was no statistically significant change from baseline in serum concentrations of L and Z in the P group over the study period ($p > 0.05$, for all) [Fig. 3A and B].

TZ* = total Z concentrations which includes MZ and Z

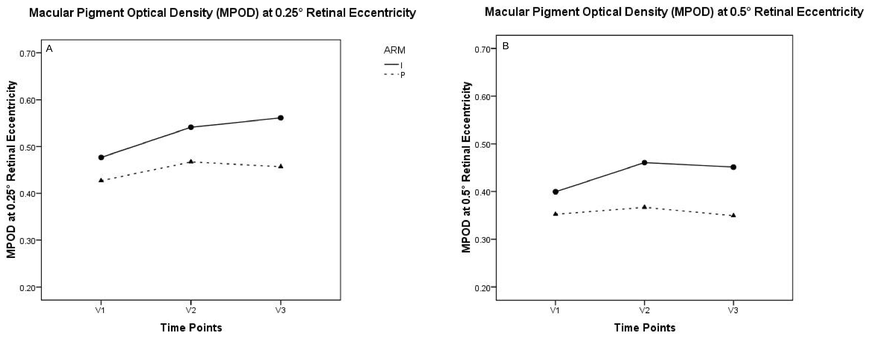
Figure 3. Serum Concentrations of Lutein and Zeaxanthin



Macular Pigment Optical Density

There was a statistically significant increase in MPOD at 0.25° and 0.5° retinal eccentricity from baseline at V2 and V3 in the I group of the study ($p < 0.005$, for all). As expected, there was no statistically significant change in MPOD over the study period, at any eccentricity measured, in the P group ($p > 0.05$, for all) [e.g. Fig. 4A and B].

Figure 4. Macular Pigment Optical Density



Clinical Pathology Analysis

Statistically significant differences from V1 to V3 were identified in 10 of the variables assessed and are highlighted in yellow in Table 1 (some increased and some decreased from baseline). However, and most importantly, all variables at each visit (with the exception of LDL, which had a baseline value outside the normal reference range) were compared with biological variation data tables at http://www.westgard.com/biodatabase1.htm, and were found to be within the normal reference range provided.

While LDL also appeared to show a significant difference between visits in the I group ($p = 0.01$), total cholesterol did not show any significant difference between visits ($p = 0.79$), and therefore it is unlikely to be of any medical significance. Further investigation is ongoing to confirm this.

Table 1. Clinical Pathology Variables

		INTERVENTION GROUP			PLACEBO GROUP		
Pathology variable	**Ref. Range (Unit)**	**V1**	**V3**	**p value**	**V1**	**V3**	**p value**
Sodium	135-145 (mmol/L)	139.42	139.26	0.51	139.26	139.26	1.00
Potassium	3.3-5.3 (mmol/L)	4.16	4.55	0.01	4.26	4.43	0.04
Chloride	98-107 (mmol/L)	104.05	98.89	0.32	104.05	103.11	0.15
Urea	2.5-7.7 (mmol/L)	4.72	5.03	0.23	5.31	5.37	0.76
Creatinine	40-90 (µmol/L)	75.11	76.84	0.42	77.00	74.68	0.15
Total protein	64-83 (g/L)	72.63	71.05	0.10	71.63	70.05	0.12
Albumin	37-52 (g/L)	44.47	44.58	0.82	43.53	44.21	0.30
Globulins	21-36 (g/L)	28.16	26.47	0.11	28.11	26.37	0.07
Total bilirubin	3.4-21.0 (µmol/L)	8.73	8.21	0.59	8.05	8.77	0.29
Alanine Aminotransferase	0-55 (IU/L)	24.32	19.42	0.18	22.47	23.16	0.63
Aspartate Aminotransferase	5-36 (IU/L)	20.37	19.05	0.16	22.16	21.89	0.81
Alkaline Phosphate	40-150 (IU/L)	78.84	74.63	0.41	79.00	79.95	0.80
Gamma GT	9-36 (IU/L)	33.84	25.05	0.29	25.16	23.89	0.42
Cholesterol total	**<5.0 (mmol/L)**	5.21	5.24	0.79	**5.26**	**4.92**	**0.02**
Triglycerides	0.60-1.70 (mmol/L)	1.38	1.66	0.13	1.10	1.09	0.93
HDL	1.00-1.55 (mmol/L)	1.46	1.49	0.63	1.54	1.51	0.46
Direct LDL	**<3.0 (mmol/L)**	**3.03**	**3.25**	**0.01**	3.13	2.98	0.23
Calcium	2.10-2.60 (mmol/L)	2.38	2.35	0.33	2.36	2.36	0.80
Phosphate	0.80-1.56 (mmol/L)	1.16	1.14	0.63	1.10	1.09	0.82
Magnesium	0.65-1.10 (mmol/L)	1.00	0.95	0.01	0.98	0.92	0.00
Uric Acid	155-394 (µmol/L)	263.47	273.47	0.19	274.68	271.74	0.76
Glucose	3.1-6.1 (mmol/L)	5.31	5.77	0.11	5.03	4.94	0.50
High Sens. Reactive Protein	<5.0 (mg/L)	4.00	3.31	0.57	1.49	4.18	0.40
Full Blood Count							
White cell count	3.88-10.49 (10e9/L)	7.07	6.79	0.24	5.97	6.92	0.10
Red cell count	3.73-5.02 (10e12/L)	4.53	4.58	0.35	4.64	4.58	0.30
Haemoglobin	**11.3-15.2 (g/dL)**	**14.23**	**13.91**	**0.03**	**14.46**	**13.85**	**0.01**
Haematocrit	**0.323-0.462 (L/L)**	**0.40**	**0.41**	**0.01**	0.40	0.41	0.38
MCV	**83.1-99.1 (fL)**	**87.93**	**90.41**	**0.00**	**87.06**	**89.42**	**0.00**
MCH	**28.3-33.9 (pg)**	**31.42**	**30.38**	**0.00**	**31.15**	**30.28**	**0.00**
MCHC	**32.1-36.6 (g/dL)**	**35.75**	**33.62**	**0.00**	**35.78**	**33.88**	**0.00**
Platlets	164-382 (10e9/L)	295.47	287.00	0.24	313.28	299.00	0.08
Diff. White Cell Count							
Neutrophils	1.91-7.16 (10e9/L)	4.39	4.05	0.15	3.44	4.18	0.16
Lymphocytes	1.01-3.13 (10e9/L)	1.85	1.86	0.92	1.72	1.87	0.04
Monocytes	0.19-0.68 (10e9/L)	0.42	0.39	0.23	0.36	0.40	0.21
Eosinophils	0.05-0.51 (10e9/L)	0.25	0.27	0.62	0.24	0.23	0.79
Basophils	0.02-0.15 (10e9/L)	0.07	0.07	0.71	0.10	0.07	0.10
L. unstained cells	**0.00-0.30 (10e9/L)**	0.13	0.13	0.81	**0.12**	**0.16**	**0.00**

Ref.: Pearson TA et al., Circulation 2003; 107:499-511 : Non Fasting Specimen: Serum/ Plasma Fl. Oxalate/ Whole blood EDTA

CONCLUSION

This double-blind, randomized placebo controlled trial showed significant increases in serum concentrations of the macular carotenoids, and MPOD at 0.25° and 0.5° retinal eccentricity, following supplementation with a formulation containing 10.9 mg MZ, 5.9 mg L and 1.2 mg Z.

Of note, MOST N is the first study to investigate, and report on, the safety of human consumption of all three macular carotenoids, including MZ. We conclude that the consumption of MZ, L and Z does not produce any medically significant changes in the pathology variables tested.

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